

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658007	(X3) Date Survey Completed 12/19/2025
Name of Provider or Supplier Doctors Center Hospital-Orlando Health- Bayamon	Street Address, City, State Callej #9 Hermanas Davilas, Bayamon, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Doctors Center Hospital-Orlando Health-Bayamon on December 18, 2025 and December 19, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on December 19, 2025.
D2094	<p>ROUTINE CHEMISTRY CFR(s): 493.841(e)</p> <p>(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), Certification and Survey Provider Enhanced Report (CASPER) Report 0155D scores, proficiency laboratory records and interview with the laboratory director on December 18, 2025 at 2:00 PM, it was determined that the laboratory failed to take corrective action when obtained an unsatisfactory score for the subspecialty of routine chemistry in the analytes of total bilirubin in the third proficiency testing event of the year 2024, chloride in the second proficiency testing event of 2024, and sodium in the second proficiency testing event of 2024. The finding includes: 1. The PRPTSP and Casper Report 0155D scores, showed that the laboratory obtained the following unsuccessful scores: Analyte: total bilirubin a. Third testing event year 2024 - 60% Analyte: chloride a. Second testing event year</p>

2024 - 40% Analyte: sodium a. Second testing event year 2024 - 0% 2. The laboratory proficiency records were reviewed on December 18, 2025 at 2:00 PM, and showed that the laboratory failed to take corrective action when the unsatisfactory score was received in the following analytes: total bilirubin analyte in the third proficiency testing event of the year 2024, chloride in the second proficiency testing event of 2024, and sodium in the second proficiency testing event of 2024. 3. The laboratory director confirmed on December 18, 2025 at 2:05 PM, that the laboratory failed to take corrective action when obtained an unsatisfactory score in the total bilirubin, chloride and sodium analytes in the proficiency testing events previously mentioned of the year 2024.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

1. Based on Cobas system (SN-11581) preventive maintenance log records review (year 2025) manufacturer's instructions and interview with the general supervisor on December 18, 2025 at 1:10 P.M., it was determined that the laboratory failed to follow the manufacturer's instructions regarding to the established preventive maintenance of the system. The findings include: a. The laboratory uses Cobas 221 System to perform arterial blood gases tests. b. On December 18, 2025 at 1:10 P.M. , the Cobas 221 (SN 11581) preventive maintenance records were reviewed. The manufacturer's requires to perform the following daily and weekly maintenance : check fill levels, printer paper (daily) and clean fill port and sample drip tray (weekly). c. On December 18, 2025 at 1:12 P.M., the daily maintenance log records review showed that the laboratory did not monitor nor document the daily and weekly maintenance the following days: 12/1/25, 12/2/25, 12/3/25, 12/10/25, 12/11/25, 12/12/25, 12/16/25, 12/17/25 and 12/18/25. d.The laboratory general supervisor confirmed on December 18, 2025 at 1:15 P.M., that the laboratory did not follow the manufacturer's instructions regarding to preventive maintenance of the system. The laboratory processed and reported 35 ABG patient samples those days. 2. Based on Cobas system (SN-11581) preventive maintenance log records review (year 2025) manufacturer's instructions and interview with the general supervisor on December 18, 2025 at 1:10 P.M., it was determined that the laboratory failed to follow manufacturer's instructions regarding to the established room temperature and relative humidity requires for the function of the system. The findings include: a. The laboratory uses Cobas 221 System to perform arterial blood gases tests. b. The manufacturer's instructions requires to monitor and document daily the room temperature and relative humidity. The manufacturer's require a room temperature range of 15 C to 31 C and a relative humidity range of 20-85 % for patient samples processing. c. On December 18, 2025 at 1:12 P.M., the maintenance log records review showed that the laboratory did not monitor nor document the room temperature and relative humidity the following days: 12/1/25, 12/2/25, 12/3/25, 12/10/25, 12/11/25, 12/12/25, 12/16/25, 12/17/25 and 12/18/25. d.The laboratory general supervisor confirmed on December 18, 2025 at 1:15 P.M., that the laboratory did not follow the manufacturer's instructions regarding to monitor and document the established room temperature and relative humidity daily . e. The laboratory processed and reported 35 ABG patient samples those days.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on lack arterial blood gases (ABG) calibration verification records review (years 2024 - 2025) and laboratory general supervisor interview on December 18, 2025, at 1:00 P.M. , it was found that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the arterial blood gases tests processed by the Cobas b221 system ,when processed and reported 8,655 out of 8,655 ABG test from January 1, 2025, to November 2025. The findings include: 1. The laboratory used the Cobas b221 system (SN 11581 and 11516) to perform ABG tests. 2. The records showed that calibration verification procedures were perform each 6 month and scheduled for June and December of each year. 3. The laboratory general supervisor confirmed on December 18, 2025 at 1:10 P.M.that the laboratory failed to ensure that calibration verification will be performed each six months. 4. The laboratory processed and reported 8,655 out of 8,655 ABG test from January 1, 2025, to November 2025.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

Based on lack of arterial blood gases results comparison records (year 2024-2025) and laboratory general supervisor interview on December 19, 2025 at 11:00 A.M. it was determined that the laboratory failed to evaluate and define twice a year the relationship between the ABG test result perform between the different system since January 2024 (Cobas SN 11581 and SN 11516). The findings include: 1. The laboratory performed ABG by two Cobas (SN- 11581 and SN- 11516) systems. 2. The laboratory did not evaluated twice a year the relationship of the ABG results

perform between the different systems since January 2024. 3. The laboratory general supervisor confirmed on December 19, 2025 at 11:00 A.M. that the laboratory failed to evaluate twice a year the ABG results perform between the different systems.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on arterial blood gases (Cobas system) preventive maintenance log records review , calibration verification records and arterial blood gases results comparison records (year 2025) and interview with the laboratory supervisor on December 18, 2025 at 2:00 P.M. AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the analytic quality control requirements. Refer to D5411, D5439 and D5775.

D6144

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:
Based on arterial blood gases (Cobas system) preventive maintenance records review , lack of calibration verification record and of ABG results comparison records (year 2024-2025) and interview with the laboratory supervisor on December 19, 2025 at 1: 00 P.M. it was determined that the laboratory general supervisor failed to carry out successful day to day supervision in the arterial blood gases department . Refer to D5411, D5439 and D5775.